Application No.: 10/530,108
Filing Date: April 1, 2005

AMENDMENTS TO THE CLAIMS

1. **(Currently amended)** A process for <u>amplifying TALL-104 lymphocytes in a homogeneous system within a multi-chamber stack, single fermentation unit comprising:</u>

adding into the multi-chamber stack an inoculum of at least 0.7x10⁶ cells/ml in an initial volume of 1/10 to 1/6 of the muti-chamber stack final volume;

amplifying the cell number by adding a volume of complete medium corresponding to that contained in the multi-chamber stack; and

recovering at least 1x10⁹ cells grown in homogeneous conditions.

the expansions of TALL lymphocytes, wherein at least 1x10⁹ cells are grown in homogeneous conditions in a single fermentation unit.

- 2. (Canceled)
- 3. (Canceled)
- 4. (Canceled)
- 5. (Currently amended) The process as claimed in claim 13, wherein said process for amplifying TALL-104 lymphocytes the expansion in the homogeneous system is preceded by a process of pre–expansion in a flask until obtaining a number of cells in an amount comprised from 0.7 to 1x10⁸.
- 6. (Currently amended) The process as claimed in claim 15, wherein the cellular density of the inoculum is at least $0.7x10^6$ cells/ml and is preferably equal to $0.75x10^6$ cells/ml and, at the harvest time, the density is lower than $2x10^6$ cells/ml, preferably than $1x10^6$.
- 7. (Currently amended) The process as claimed in claim <u>1</u> [[4]], wherein the <u>multi-chamber stack Cell-Factory</u> is a 10-chamber unit.
- 8. (Currently amended) The process as claimed in claim 1, wherein <u>said TALL-104</u> lymphocytes are selected from the group consisting of: TALL-104, TALL-107, TALL-103/2 cell lines, optionally genetically modified.
 - 9. (Canceled)
- (Currently amended) The process as claimed in Claim 1, wherein the complete culture medium in the <u>multi-chamber stack cell-factory</u> amplification phase also comprises 10% maximum human serum, preferably in the range of 4 to 6%, still more preferably of 5%, and interleukin in a concentration comprised from 80 to 120 IU/ml.

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- 11. **(Currently amended)** The process as claimed in claim 10, wherein interleukin-2 is added to the cell culture every 48-90 hrs.
- 12. (Currently amended) The process as claimed in claim 10, wherein the cell amplification growth in the homogeneous system takes place in an antibiotic-free culture medium.
- 13. (Currently amended) A process for the preparation of frozen bags of TALL-104 lymphocytes in an amount of at least $1x10^9$ cells, wherein comprising using the process according to Claim 1 is used.
- 14. (Previously presented) The process as claimed in claim 13, wherein the bag is sealed transversally to <u>a the</u> bag filling collet at least in two points to create at least a sampling chamber containing a cell culture volume ranging from 0.1 to 1 ml, physically separated from the culture contained in the bag to perform quality controls.
- 15. (Currently amended) A process for the preparation of a therapeutic dose of at least 1x10⁹ TALL-104 lymphocytes in a homogeneous culture comprising using the process according to Claim 1.

16. (Canceled)

- 17. **(Withdrawn, currently amended)** TALL<u>-104</u> lymphocytes obtainable according to the process of Claim 1 wherein said lymphocytes are characterised by a CD3⁺ and CD8⁺ immunologic markers expression of 98% min, preferably ≥99%, and by the CD56⁺ marker expression of 95% at least, preferably ≥97%.
- 18. **(Withdrawn, currently amended)** TALL<u>-104</u> lymphocytes according to claim 17 characterised by a biological activity, determined by a cytotoxicity assay on appropriate target cells, equal to at least 70% of the control.

19.-24. (Canceled)

- 25. (New) The process as claimed in claim 10 wherein said complete culture medium comprises 4-6% human serum.
- 26. (New) A process according to claim 10, wherein said TALL-104 lymphocytes are genetically modified.
- 27. (New) The process as claimed in claim 26, wherein the bag is sealed transversally to a bag filling collet at least in two points to create at least a sampling chamber containing a cell

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culture volume ranging from 0.1 to 1 ml, physically separated from the culture contained in the bag to perform quality controls.

28. (New) The process of claim 15, wherein the complete culture medium in the cell-factory amplification amplification phase also comprises 10% maximum human serum and interleukin in a concentration from 80 to 120 IU/ml.